MAY 12 2000

K000162

ALARA™ INCORPORATED

14 510(k) Summary

MetriScan Bone Density System

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c).

Submitter: Alara, Inc.
2545 Barrington Court
Hayward, CA 94545

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Date Prepared: January 14, 2000

Trade Name: MetriScan™ Bone Density System

Common Name: Bone Densitometer

Classification Name: Bone Densitometer (21 CFR section 892.1170)

Predicate Device:		
	Schick accuDEXA	510(k) K971735 and K981124
	CompuMed OsteoGram 2000 and OsteoGram	510(k) K984285 Preamendment
	Lunar PIXI	510(k) K970224

Product Description:
MetriScan™ is a self-contained, table-top system that performs digital radiographic absorptiometry (RA) to assess Bone Mineral Density (BMD) of the phalanges. The device acquires x-ray images of the middle phalanges of the 2nd, 3rd, and 4th digits of the non-dominant hand, automatically analyzes the images, estimates bone density, and compares the results to normative and age-specific reference population data. The comparison of the patient's estimated relative BMD value to the normative reference data generates a T-score, which can be used by the physician as an aid to diagnose osteoporosis or osteopenia and to estimate fracture risk. The estimate of relative BMD can be used to monitor changes in bone mass over time. The comparison of the patient's estimated relative BMD value to the age-specific reference data generates a Z-score, which can be used by the physician as an aid to diagnose other disorders affecting bone mass. Z-scores are meaningful only when the patient's gender and ethnicity matches that of the reference population data.

Indications for Use:
MetriScan is indicated for use in estimating relative bone mineral density (BMD). The estimate of relative BMD and T-score may be used as an aid to the physician in assessing fracture risk, and for monitoring changes in bone mass over time.

Rationale for Substantial Equivalence
The MetriScan has the same or similar indications for use as the predicate devices. The MetriScan shares the same technological characteristics as the predicate devices. However, the descriptive characteristics may not be sufficiently precise to assure substantial equivalence. Therefore, Alara has carried out validation and performance testing. The results of this testing demonstrate that the MetriScan is substantially equivalent to the predicate devices.

Safety and Effectiveness Information:
MetriScan is a Class II medical device, and a Class I laser product. MetriScan complies with applicable FDA and international standards pertaining to electrical, mechanical, EMC, and radiation safety of medical and /or laser devices.

Alara has performed in-vitro and in-vivo studies to determine MetriScan accuracy and precision. Accuracy is represented by the strength of the correlation between MetriScan results and known densities. The results of the studies showed that the MetriScan results correlate highly (R=0.98) with phantom densities determined by Computed Tomography (CT). MetriScan results also correlate highly (R=0.95) with a predicate. The studies also demonstrated that the MetriScan estimated relative BMD values are very repeatable, even with repositioning, over the full range of densities seen clinically. The high precision demonstrated through the in-vitro and in-vivo studies support the use of MetriScan estimated relative BMD values for monitoring changes in bone mass over time.

A normative and reference database has been developed in a clinical study which allows the calculation of T-scores for each patient, and Z-scores for patients whose gender and ethnicity match that of the reference database.

Conclusion:
MetriScan performance tests and clinical studies have demonstrated that the MetriScan is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2000

Diane King
Vice President of Regulatory Affairs
ALARA Inc.
2545 Barrington Ct.
Hayward, CA 94545-1134

Re: K000162
MetriScan Bone Density System
Dated: January 14, 2000
Received: January 19, 2000
Regulatory class: II
21 CFR 892.1170/Procode: 90 KGI

Dear Ms. King:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

3 Intended Use

510(k) Number (if known): K000162

Device Name: MetriScan™ Bone Density System

Indications for Use: MetriScan is indicated for use in estimating relative bone mineral density (BMD). The estimate of relative BMD and T-score may be used as an aid to the physician in assessing fracture risk, and for monitoring changes in bone mass over time.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000162